EXHIBIT 8

Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)

FDA's Adverse Event Reporting System (FAERS)

FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files

FDA Adverse Event Reporting System (FAERS) Public Dashboard

FDA Adverse Event Reporting System (FAERS) Electronic Submissions

Content current as of:
12/30/2024

Regulated Product(s)
Drugs

What is FDA posting?

The following reports list potential signals of serious risks/new safety information that were identified using the FAERS database during the indicated quarter. Data from AERS was moved to FAERS for the launch of FAERS on September 10, 2012. The appearance of a drug on this list does not mean that FDA has concluded that the drug has the listed risk. It means that FDA has identified a ***potential safety issue***, but it does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions, including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize the risk.

FDA wants to emphasize that the listing of a drug and a potential signal of a serious risk/new safety information on this Web site does not mean that FDA has determined that the drug has the risk. FDA is not suggesting that healthcare providers should not prescribe the drug or that patients taking the drug should stop taking the medication while an evaluation of the potential safety issue is being conducted. Patients who have questions about their use of the identified drug should contact their health care provider.

FDA will complete its evaluation of each potential safety issue and may issue additional public communications as appropriate.

Why is FDA posting this information?

FDA is posting these reports in accordance with Title IX, Section 921 of the Food and Drug Administration Amendments Act of 2007 (FDAAA; see insert). FDA will publish a new list of potential signals of serious risks/new safety information identified each quarter.

Title IX, Section 921 of the Food and Drug Administration Amendments Act 2007 (FDAAA) (121 Stat. 962) amends the Federal Food, Drug and Cosmetic Act (FDCA) to add a new subsection (k)(5) to section 505 (21 U.S.C. 355).

This section in FDAAA, among other things, directs FDA to "conduct regular, bi-weekly screening of the Adverse Event Reporting System [AERS] database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter. When a potential signal of a serious risk is identified from AERS data, it will

be posted in the required report in the quarter in which it is first identified. A potential signal of a serious risk may in some cases constitute new safety information as defined in FDAAA (newly created section 505-1(b)(3) of the FDCA) which includes, among other things, information derived from adverse event reports about a serious risk associated with use of a drug that FDA has become aware of since the drug was approved or, for drugs that have REMS, since the REMS was required or last assessed. FDA will post each potential signal of a serious risk in the quarter in which it is first identified. If additional new safety information is developed concerning a potential signal that has already been posted, it will be addressed by FDA in new safety communications, but will not appear again as a new quarterly posting.

How was the list generated?

FDA staff in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) regularly examine the FAERS database as part of routine safety monitoring. When a potential signal of a serious risk is identified from FAERS data, it is entered as a safety issue into CDER's Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) or into CBER's Therapeutics and Blood Safety Branch's Safety Signal Tracking (SST) system. Potential signals of serious risks are normally based upon a collection of FAERS reports, although a single FAERS report could lead to further evaluation of a potential safety issue.

What information is provided?

The table in each report lists the names of products and potential safety issues that were entered into the above CDER or CBER tracking systems where the FAERS database identified (or contributed to identification of) the potential safety issues. Additional information on each potential safety issue, such as an FDA Drug Safety Communication, is also provided.

A new report will be made available each quarter showing newly identified potential signals of serious risks/new safety information identified from the FAERS database during the previous quarter. Information from previous quarters with updates will remain available on the website until an FDA regulatory action has been taken. FDA actions may include a determination either that a) the drug is not associated with the risk and therefore no regulatory action is required, or b) the drug may be associated with the risk, and one of the following is required: a modification to the product labeling; development of a REMS; marketing suspension or withdrawal; or gathering additional data to characterize the risk. After FDA has determined that either no regulatory action is required or has taken a regulatory action for each issue on a quarterly report, no further updates will be made and the quarterly report will be archived. **Archived Reports**

Quarterly Reports

2024

- January - March 2024
- April - June 2024
- July - September 2024

2023

- January - March 2023
- April - June 2023
- July - September 2023
- October - December 2023

2022

- January - March 2022
- April - June 2022
- July - September 2022
- October - December 2022

2021

- January - March 2021
- April - June 2021
- July - September 2021
- October - December 2021

2020

- January - March 2020
- April - June 2020
- July - September 2020
- October - December 2020

2019

- July - September 2019

2018

- January - March 2018
- April - June 2018
- July - September 2018
- October - December 2018

2017

- January - March 2017
- April - June 2017
- July - September 2017
- October - December 2017

2016

- January - March 2016
- April - June 2016

2015

- April - June 2015
- July - September 2015

Resources

- Report a Serious Medical Product Problem Online
- Drugs@FDA
- DailyMed (National Library of Medicine)